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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,711	06/26/2006	Aaron Davidson	JPD-4398-555	8001
23117	7590	08/10/2010	EXAMINER	
NIXON & VANDERHYE, PC			BLIZZARD, CHRISTOPHER JAMES	
901 NORTH GLEBE ROAD, 11TH FLOOR			ART UNIT	PAPER NUMBER
ARLINGTON, VA 22203			3771	
			MAIL DATE	DELIVERY MODE
			08/10/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/584,711	DAVIDSON ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	CHRISTOPHER BLIZZARD	3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 June 2010.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-54 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-54 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/18/10, 7/28/10, 7/30/10</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

1. This office action is in response to amendment filed 6/18/10. As directed claims 1, 38, and 46 have been amended, claims 32-37 have been cancelled and no claims have been added. Therefore this application has claims 1-31 and 28-54 pending.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-18, 20-24, 26 31-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berthon-Jones (6,123,071) in view of Illing (443,191) and further in view of Lee (4,915,105).

4. Regarding claim 1, Berthon-Jones discloses a breathing arrangement for use between a patient and a structure to deliver gas to a patient, a CPAP device (column 2, lines 31-32), the breathing arrangement comprising; a patient interface including a mouth covering assembly including a flexible cushion (46) structured to sealing engage around an exterior of a patient's mouth in use (column 4, lines 41-48), a nose assembly (fig. 2, around #44) sealing engaging with a the nasal passages of a patient (column 6, lines 24-26), and a flexible element (64) connecting the mouth covering assembly and the nose assembly (column 6, lines 44-45; column 7, lines 18-20); one inlet conduit (50) to deliver breathable gas into the nose assembly (fig. 3a); and a headgear assembly connected to the mouth covering assembly or nose assembly (column 5, lines 4-8),

which is inherently removable. Berthon-Jones does not teach the nose assembly being a nozzle assembly including a pair of nozzles structured to sealingly engage within nasal passages of a patient's nose. Illing teaches a breathing arrangement with a mouth covering (fig. 3) as well as a nozzle assembly including a pair of nozzles (fig. 3) structured to sealingly engage within nasal passages of a patient's nose. It would have been obvious to one of ordinary skill in the art at the time of the invention to replace the nose assembly of Berthon-Jones with nozzles as taught by Illing in order to provide the advantage of less skin contact and irritation around the nose. Further Berthon-Jones discloses the used of a head gear assembly (coulumn 5, lines 4-8) but does not disclose the headgear assembly being attached to one of the mouth covering assembly and the nozzle assembly and in use following two vectors to maintain the breathing arrangement in a sealed position. Lee teaches a headgear assembly that is connected in a removable way (fig. 1) to a breathing arrangement that is use follows two vectors to maintain the breathing arrangement in a seal position on the patient's face. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the breathing arrangement of Berthon-Jones and Illing with a headgear assembly as taught by Lee in order to provide the advantage of a more secure fit.

5. Regarding claim 2, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches a first chamber (54) formed by the mouth covering a second chamber (52) formed by the nose assembly, analogous to the nozzle assembly of Thornton.

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6. Regarding claim 3, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the flexible element (64) being a conduit that allows gas to pass between the first and second chamber (fig. 4b) (column 7, lines 8-10).

7. Regarding claim 4, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Illing teaches the nozzle assembly connected to an air inlet conduit (fig 1).

8. Regarding claim 5, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the mouth covering adapted to connected to an inlet conduit (50) to deliver breathable gas to the patients mouth (fig. 4b).

9. Regarding claim 6, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the mouth chamber (54) and the nose chamber (52) being fluidly connected by a duct and this forming a single chamber (fig. 4b).

10. Regarding claim 7, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the structure to be integrally formed as a one piece structure (column 6, lines 35-39).

11. Regarding claim 8, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the cushion (46) having a face contacting portion (fig. 4a, around #46) and a non face contacting portion (fig. 4a, around #56) removably attached to a rigid frame (42).

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12. Regarding claim 9, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the sides of the cushion partially collapsing (column 4, lines 62-67), and thus considered to be a gusset portion.

13. Regarding claim 10, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the cushion having a side wall (fig. 4b), a rim extending from the side wall (fig. 4b), and a membrane surrounding the rim (fig. 4b).

14. Regarding claim 11, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Illing teaches the nozzle being mounted upon a side wall of the mouth covering (fig. 3).

15. Regarding claim 12, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Illing teaches the nozzle being angled with respect to the side wall (fig. 3).

16. Regarding claim 13, the combination of -Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the inner edge of the membrane forming an aperture have a general oval shape (fig. 2, around #56 and #54).

17. Regarding claim 14, the combination of -Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the mouth cushion having an arcuate protruding portion along the upper and lower edge, in that it is curved and the ends protrude more than the center (column 4, lines 25-27)(fig. 1c).

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18. Regarding claim 15, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the rim being provided on lateral sides of the side walls of the cushion (fig. 2).

19. Regarding claim 16, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the membrane being thinner than the rim (fig. 4b)(column 4, lines 61-67).

20. Regarding claim 17, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Lee teaches the headgear assembly routed around the top of the patient's ears (fig. 1).

21. Regarding claim 18, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Lee teaches the headgear assembly being able to be rotated with respect to the patient interface so as to adjust a position of the headgear assembly with respect to the patient in use, without detaching the headgear assembly and the patient interface in that the headgear assembly includes d-rings that the straps of the headgear assembly could be rotated about (fig. 1).

22. Regarding claim 20, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the patient interface having a frame (48) with an inlet conduit (50) coupled at one end of it (fig. 3a) and an anti-asphyxia valve (56) coupled at the opposite side (fig. 3a).

23. Regarding claim 21, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the device wherein the nose

assembly, analogous to the nozzle assembly taught by Thornton, in not in fluid communication with the mouth cushion (column 6, lines 13-15).

24. Regarding claim 22, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the body contacting portions to be made of silicone rubber (column 4,61-62), which could be considered to be a gel-like material.

25. Regarding claim 23, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the nose assembly, and thus the nozzles being formed separately from the cushion.

26. Regarding claim 24, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the frame having corrugations (30) (fig. 4a) that would add flexibility to the frame.

27. Regarding claim 26, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein the Illing teaches the nozzles being mount within rounded recesses (fig. 1) (page 1, lines 78-81).

28. Regarding claim 31, the combination of Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the cushion (46) having a boomerang shape (fig. 2).

29. Regarding claim 38-45, the combination of Berthon-Jones, Illing and Lee teach the claimed invention above, further wherein Berthon-Jones teaches the membrane having a substantially flat profile (fig. 2).

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30. Regarding claims 46-54, the combination Berthon-Jones, Illing and Lee teach the claimed invention wherein Berthon-Jones teaches the side wall of the cushion (46) being mounted in a removable manner to the frame (fig. 4b).

31. Claims 19, 25 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over over Berthon-Jones (6,123,071), Illing (443,191) and Lee (4,915,105) as applied to claim 1 above, and further in view of Trimble (4,782,832).

32. Regarding claim 19, the combination of Berthon-Jones, Illing and Lee teach the claimed invention except for the specific structure of the headgear assembly including a snap fit. Trimble teaches a breathing arrangement with a headgear assembly (24) (fig. 1) that is connected to the patient interface using clips and Velcro (column 6, lines 60-68, column 7, lines 1-2), analogous to a snap fit. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the device of Berthon-Jones, Illing and Lee with the snap fit apparatus present in the headgear as taught by Trimble in order to provide the add vantage easily being able to put on the breathing arrangement.

33. Regarding claims 25 and 27-30, the combination of Berthon-Jones, Illing and Lee teach the claimed invention except for the nozzles having a concertina configuration, a varying conduit cross section, gusset portion, a surrounding thin membrane and nozzle support element. Trimble teaches a nozzle assembly wherein the nozzles including a concertina configuration (fig. 2), a varying conduit cross section (fig. 3), gusset portion (fig. 2 and 3), a surrounding thin membrane (fig 3) and nozzle support element (34) (fig. 2). It would have been obvious to one of ordinary skill in the art at the time of the

invention to modify the nozzles of Berthon-Jones, Illing and Lee with the nozzle configuration as taught by Trimble in order to provide the add vantage a better sealing nozzle assembly.

***Response to Arguments***

34. Applicant's arguments with respect to claims 1-31 and 38-54 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday-Friday, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Christopher Blizzard/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771